

Claims

1. A process for preparing a sterile ready-to-use aqueous pharmaceutical formulation comprising a high molecular weight hyaluronic acid salt (HA) at a specified concentration, comprising the steps of:
 - providing an aqueous formulation comprising high molecular weight HA at a concentration of less than the specified concentration;
 - passing said aqueous formulation through a filter having a pore size less than 0.45 μm ;
 - concentrating said aqueous formulation by applying a vacuum and boiling off water until said specified concentration is reached.
2. Process according to claim 1, wherein after the concentrating step, the pharmaceutical formulation is filled in sterile recipients ready for use, or emptied into sterile tanks and subsequently filled in sterile recipients ready for use.
3. Process according to claim 1 or 2, wherein the vacuum applied in the concentrating step is at an absolute pressure less than 200 millibars.
4. Process according to the preceding claim, wherein the vacuum is at a pressure in the range of 30 to 60 millibars.
5. Process according to any of the preceding claims, wherein the average molecular weight of HA is in the range of 800'000 to 5'000'000 Daltons.
6. Process according to any one of the preceding claims, wherein the filter has a pore size of 0.22 μm or less.

7. Process according to any one of the preceding claims, wherein, during the concentration step, the concentration of HA is measured in real time and the vacuum boiling process is stopped automatically when the specified concentration is measured.

8. Process according to any of the preceding claims, wherein the HA concentration is measured with a spectrophotometer sensing wave radiation absorption in the formulation.

9. Process according to any one of the preceding claims, wherein excipients are added to the formulation after the filtration step, and wherein the conductivity of the HA formulation is measured in real time until the amount of excipients reaches the required value.